

Pharma infra: Gearing for new realities

As India Pharma Inc makes the shift from volume-based care to value-based care, it has to invest in robust R&D and manufacturing infrastructure, both physical and digital, to accelerate drug development and enable speed to market



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A complex and evolving regulatory landscape, the combined threat of existing and emerging diseases, innovative new technologies, need for agile R&D and manufacturing operational models, etc. are driving pharma and lifesciences companies to take diverse steps to increase their innovation potential, curb R&D and manufacturing costs, improve productivity and reduce time to market. Ramping up their physical and digital infrastructure is a key aspect of this endeavour and this requires careful design, equipment and technology planning and operation strategies.

For instance, animal facilities that are key to accurate R&D results or regulatory compliance of products need to be built by taking into account various aspects like compliance with standards in bioethics, animal and employee welfare, etc.

Likewise, building a combined GMP and bio-containment environment is a multi-faceted undertaking that requires an equilibrium among various sets of requirements like biosafety risk assessment, use of new production technologies, use of modular solutions to ensure GMP and biocontainment, air management systems to maintain hygiene and biosafety procedures, etc.

So, in this article, let's examine some of the key considerations for the design and construct of multi-product pharma R&D and manufacturing facilities.

Flexibility and adaptability: It has become an imperative for new-age pharma facilities to be agile, adaptable and flexible, be it for research or manufacturing, to get the best outcomes, meet evolving market demands and regulatory expectations. Flexibility includes the ability to expand and allow reconfigurations easily to aid a variety of uses. And, as companies expand their markets and product portfolios, it has become vital to be efficient and get rid of the need for new facilities for every new product. Thus, these facilities have to be multi-functional and multi-disciplinary, designed and built using optimised layouts and workflows, to encourage innovation, ensure the highest standards of quality and support the shift towards value-based care. As a result, the design of pharma infrastructure too is developing to meet budding demands and trends.

Modern pharma labs and facilities have to be logically laid out and all the resources should be easily available. They have to be modular, flexible and scalable, said SM Mudda, Managing Director, Misom Labs, speaking at the Pharma LabNext Conclave 2021, recently organised by *Express Pharma*. He added that modern labs handle a lot of potentially hazardous compounds for highly potent drugs. So, lab design has to account for containing them while you're working in the lab. Likewise, in manufacturing, facility design should assure better controls, quality and safety measures.

Speaking at the same event, Naresh Narasimhan, Principal Architect and Managing Partner, Venkataramanan Associates, explained that designs for labs should not be inflexible spaces that will not be suitable five years later when an organisation's

requirement changes. On the contrary, with the help of a lifecycle cost analysis, they should be modified or built in such a way that they can be refigured quickly to accommodate the extra services that will be needed in the times to come.

He asserted that flexibility balanced with functionality to change the very nature of the laboratory itself, indicating clever engineering, is crucial while designing a lab.

To cite an example, there are pharma R&D labs with movable benches and articulated arms fixed on the ceilings that travel along with the benches to deliver services. The aim is to rapidly and effortlessly restructure a lab to suit the change in workflows and shift to new projects without undertaking huge architectural and engineering overhauls.

Cohesive and collaborative: The lifesciences industry has understood the need to function in a collaborative milieu – both internally and externally. Therefore, apart from optimising cost, resources and technical performance, pharma facilities and laboratories also have to be holistic in design. As open science and R&D partnerships become increasingly important, pharma labs have to facilitate collaboration between individuals and teams, and provide integrated synergies to encourage creativity and innovation that support project goals.

Elaborating on this point, Narasimhan detailed how earlier labs were closed rooms with maybe fire doors or access doors, where each lab did its own thing and the interaction between scientists was fairly minimal. Now, as collaboration increases in the sector, one of the innovations is creating open labs with a lot of glass. Speaking about the work done by his firm, he said, “We put a lot of glass and the desk spaces of the scientists are very close to their workstations so they can move between them very easily. The goal is always to increase output and encourage innovation. We have created a lot of spaces in the laboratories, where scientists from these different disciplines, technicians as well as business leaders are able to meet and exchange ideas easily.”

There are numerous such considerations about design, equipment and operation in new pharma manufacturing plants as well. Next-generation manufacturing, which is expected to be predictive and adaptive, will need design approaches and strategies that enable scalability, flexibility, innovation, quality and regulatory best practices.

Experts also reveal that the growing use of Internet of Things (IoT) in R&D and manufacturing environments are encouraging modular approaches in the design and construction of manufacturing facilities and labs in the lifesciences sector that will break down organisational and informational silos.



Design for technology

Pharma and lifesciences industries are in the course of upgrading processes, equipment and technology for enhanced efficiency and quicker product switches, especially since the onset of the pandemic. So, the need of the hour is to blend technical, healthcare and architectural concepts to create well-designed and effective pharma facilities that assist in optimal space utilisation and streamlining of workflows.

Yet, often it is found that the design of labs and facilities do not adequately plan for new equipment and technology solutions which can hinder productivity and cause glitches in the long run. Adoption of Lean principles in pharma infrastructure can help mitigate this challenge and usher new efficiencies.

Whether it is automation, AI or IoT or cognitive technologies, Industry 4.0 is playing out in the pharma industry. But Industry 4.0 has to be supported by Quality 4.0. Therefore, we need smart quality management systems and digitally-enabled labs and facilities. Therefore, focussing on innovation and modern technology is the need of the hour. Consequently, pharma infrastructure trends are getting shaped by the need for smart and integrated labs and manufacturing facilities, opined Mudda.

Another speaker at Pharma LabNext Conclave 2021, Archana Salil, Founder Director and Principal Architect, Arena Consultants also stressed that digitisation of lab designing is the future. She said that the adoption of robots and cobots, increasing use

of sensors, greener materials and technologies, etc. will grow increasingly in the design and build of pharma infrastructure.

She added that lab infrastructure costs will rise with digitisation, but things are going to change drastically and will move in a positive direction.

Thus, the design and build of pharma infrastructure are beginning to reflect and imbibe the emerging technology/innovation trends. For instance, automation and digitalisation have brought in an era of smaller lab equipment that can integrate multiple laboratory functions, thereby saving bench space, resources and capital.

Sustainability

The pandemic has made the world sit up and pay heed to the fact that the global environment is sensitive to human activity. So, it is no longer possible to put sustainability on the back burner. And, the pharma industry, as a key stakeholder in global health security, needs to embrace it in a big way. Concerted efforts are required to build and operate greener labs and facilities in ways that either minimise or negate their effects on the environment, especially since many organisations' existing infrastructure are not designed for sustainability.

Strategies to design and green pharma labs and manufacturing plants, be it renovating the current space or creating a new building, involve assessing the function of the facility, identifying areas that can be improved from a sustainability point of view and implementing measures, be it optimal utilisation of resources, better waste disposal systems, measures to conserve energy and water, or reducing carbon footprint.

Sustainable design comprises both, architectural and engineering considerations. For instance, overhangs, glazing, insulation, use of photovoltaic panels can help in energy efficiency. Similarly, the right HVAC systems, harvesting rainwater, sustainable lighting strategies, maximising the use of natural daylight, etc. can also help with sustainability goals. It also involves the effective use of technology to maximise the impact of eco-friendly initiatives.

Fortunately, the industry is already integrating these aspects into their labs and facilities. At a recent event organised by *Express Pharma*, in association with SAP, a few ESG leaders spoke about how pharma organisations are investing in physical and technical infrastructure to further their sustainability agendas.

Rajan Sharma, Vice President and Head Corporate EHS, Glenmark Pharmaceuticals informed that Glenmark has used smart sensors to control air control units, heaters and chillers installed at manufacturing facilities to maintain the right temperature and humidity at all times. This aids to optimise use of energy, reduce wastage, capture data and gain insights for further process optimisation.

Thakur Pherwani, Global Head SHE & Sustainability, Dr Reddy's Laboratories, detailed similar measures implemented as part of the 'Digital Lighthouse' initiative at Dr Reddy's Laboratories. The company is banking on digitalisation, be it manufacturing, quality assurance, R&D trials, to facilitate energy saving, waste reduction, productivity enhancement or equipment efficiency. The company is also looking to adopt carbon capture technology to curb emissions and alter waste into energy that can be used in different processes.

Bhavesh Trivedi, Head EHS, Zydus Cadila, explained how water conservation has been taken up in a big way at his organisation at their plant in Gujarat and the company's implementation of different trackers for water and energy consumption, etc. to gain actionable insights.

TRENDS IN PHARMA DESIGN

- ◆ Open-grid ceilings where utilities drop down for better space management
- ◆ Movable HPLC systems and work benches
- ◆ Open labs for improved collaboration
- ◆ Innovative ventilation strategies
- ◆ Use of green materials

DRIVERS OF PHARMA LAB AND MANUFACTURING FACILITY DESIGN

- ◆ Evolving regulatory requirement
- ◆ Added focus on quality
- ◆ Growing patient centricity
- ◆ Shift to personalised medicines
- ◆ Move towards Industry 4.0
- ◆ Workforce and resources management

In times to come

Design and construction of pharma infrastructure in India are evolving to blend functionality with creativity as it strives to keep pace with the industry's ventures into

new areas of innovation across products, processes, tools and functions. In the years to come, we will see many more transformations and newer trends coming into existence.

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